



CUB-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not assigned  
Group Art Unit : Not assigned  
Applicants : Jason Hill et al.  
Application No. : 09/738,742  
Filed : Dec. 15, 2000  
For : NOVEL LIPOPEPTIDES AS ANTIBACTERIAL AGENTS

New York, New York  
March 28, 2001

Hon. Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

- ☐ within three months of the application filing date;  
☒ more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97(b), submission of this Statement requires no fee. However, if for any reason a fee is due, the Commissioner is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.



Respectfully submitted,

Karen E. Brown

James F. Haley, Jr. (Reg. No. 27,794)

Attorney for Applicants

Karen E. Brown (Reg. No. 43,866)

Agent for Applicants

c/o FISH & NEAVE

1251 Avenue of the Americas

New York, New York 10020-1104

Tel.: (212) 596-9000

I Heroby Certify that this  
Correspondence is being  
Deposited with the U.S.  
Postal Service as First  
Class Mail in an Envelope  
Addressed to: ASSISTANT  
COMMISSIONER FOR  
PATENTS  
WASHINGTON, D.C. 20231 on

May 28, 2001  
Claire J. Shinnick

Signature of Person Signing



CUB-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not assigned  
Group Art Unit : Not assigned  
Applicants : Jason Hill et al.  
Application No. : 09/738,742  
Filed : December 15, 2000  
For : NOVEL LIPOPEPTIDES AS ANTIBACTERIAL AGENTS

New York, New York  
March 28, 2001

Hon. Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants make of record the following documents that are listed on the enclosed Form PTO-1449 (submitted in duplicate). Copies of the documents are enclosed herewith.

UNITED STATES PATENTS

Re. 32,310	DeBono	issued Dec. 16, 1986
Re. 32,311	DeBono	issued Dec. 16, 1986

4,396,543	DeBono	issued Aug. 2, 1983
4,399,067	DeBono	issued Aug. 16, 1983
4,482,487	Abbott et al.	issued Nov. 13, 1984
4,524,135	Abbott et al.	issued Jun. 18, 1985
4,537,717	Abbott et al.	issued Aug. 27, 1985
5,573,936	Kreuzman et al.	issued Nov. 12, 1996
5,629,288	Lattrell et al.	issued May 13, 1997
5,912,226	Baker et al.	issued Jun. 15, 1999

#### FOREIGN PATENT DOCUMENTS

EP 0 885 957 A1	published Dec. 23, 1998
WO 99/43700	published Sept. 2, 1999

#### OTHER DOCUMENTS

Alborn, W. E. Jr. et al., "Daptomycin Disrupts Membrane Potential in Growing *Staphylococcus aureus*," *Antimicrobial Agents and Chemotherapy* 35: 2282-2287 (1991).

Allen, N. E. et al. "Inhibition of Peptidoglycan Biosynthesis in Gram-Positive Bacteria by LY146032," *Antimicrobial Agents and Chemotherapy* 31: 1093-1099 (1987).

Allen, N. E. et al. "Inhibition of Membrane Potential-Dependent Amino Acid Transport by Daptomycin," *Antimicrobial Agents and Chemotherapy* 35: 2639-2642 (1991).

Baltz, R. H., "Lipopeptide Antibiotics Produced by *Streptomyces roseosporus* and *Streptomyces fradiae*," in *Biotechnology of Antibiotics*, 2d Ed., 415-435 (1997).

Bingen, E. et al. "Bactericidal Activity of Daptomycin Against Vancomycin-Resistant *Enterococcus faecium* in an in Vitro Pharmacokinetic Model," *Eur. J. Clin. Microbiol. Infect. Dis.* 10: 1062-1065 (1991).

Boeck, LaVerne D. et al. "Deacylation of A21978C, An Acidic Lipopeptide Antibiotic Complex, by *Actinoplanes utahensis*," *Journal of Antibiotics* XLI: 1085-1092 (1988).

Boeck, L.D. et al. "A54145, A New Lipopeptide Antibiotic Complex: Discovery, Taxonomy, Fermentation and HPLC," *Journal of Antibiotics* XLIII: 587-593 (1990).

Champlin, Franklin R. et al. "Cell Envelope Impermeability to Daptomycin in *Pseudomonas aeruginosa* and *Pasteurella multocida*," *Current Microbiology* 21: 367-372 (1990).

Chong, Pei Pei et al. "Physical Identification of a Chromosomal Locus Encoding Biosynthetic Genes for the Lipopeptide Calcium-Dependent Antibiotic (CDA) of *Streptomyces coelicolor* A3(2)," *Microbiology* 144: 193-199 (1998).

Debono, M. et al. "A21978C, A Complex of New Acidic Peptide Antibiotics: Isolation, Chemistry, and Mass Spectral Structure Elucidation," *Journal of Antibiotics* XL: 761-777 (1987).

Debono, M. et al. "Enzymatic and Chemical Modifications of Lipopeptide Antibiotic A21978C: The Synthesis and Evaluation of Daptomycin (LY146032)," *Journal of Antibiotics* XLI: 1093-1105 (1988).

Debono, M. et al. "Synthesis of New Analogs of Echinocandin B by Enzymatic Deacylation and Chemical Reacylation of the Echinocandin B Peptide: Synthesis of the Antifungal Agent Cilofungin (LY121019)," *Journal of Antibiotics* XLII: 389-397 (1989).

Dong, Mei-Yan et al. "Treatment of *Clostridium difficile* Colitis in Hamsters with a Lipopeptide Antibiotic, LY146032," *Antimicrobial Agents and Chemotherapy* 31: 1135-1136 (1987).

Eid, Pascale et al. "Effect of Daptomycin on the Barotropic Behavior of Dioleoylphosphatidylglycerol: An Infrared Spectroscopic Investigation," *Chemistry and Physics of Lipids* 83: 131-140 (1996).

Eliopoulos, George M. et al. "In Vitro Activity and Mechanism of Action of A21978C<sub>1</sub>, a Novel Cyclic Lipopeptide Antibiotic," *Antimicrobial Agents and Chemotherapy* 27: 357-362 (1985).

Huber, F. M. et al. "The Formation of Daptomycin by Supplying Decanoic Acid to *Streptomyces roseosporus* Cultures Producing the Antibiotic Complex A21978C," *Journal of Biotechnology* 7: 283-292 (1988).

Huber, F. M. et al. "The Synthesis of A21978C Analogs by *Streptomyces roseosporus* Cultivated Under Carbon Limitation and Fed Fatty Acids," *Biotechnology Letters* 12: 789-792 (1990).

Inokoshi, Junji et al. "Cloning and Sequencing of the Aculeacin A Acylase-Encoding Gene From *Actinoplanes utahensis* and Expression in *Streptomyces lividans*," *Gene* 119: 29-35 (1992).

Inokoshi, Junji et al. "Efficient Production of Aculeacin A Acylase in Recombinant *Streptomyces* strains," *Appl. Microbiol. Biotechnol.* 39: 532-536 (1993).

Kempton, Christoph et al. "CDA: Calcium-Dependent Peptide Antibiotics from *Streptomyces coelicolor* A3(2) Containing Unusual Residues," *Angew. Chem. Int. Ed. Engl.* 36: 498-501 (1997).

Kirsch, Lee E. et al. "Kinetics of the Aspartyl Transpeptidation of Daptomycin, a Novel Lipopeptide Antibiotic," *Pharmaceutical Research* 6: 387-393 (1989).

Lakey, Jeremy H. et al. "The Role of Acyl Chain Character and Other Determinants on the Bilayer Activity of A21978C An Acidic Lipopeptide Antibiotic," *Biochimica et Biophysica Acta* 859: 219-226 (1986).

Lakey, Jeremy H. et al. "Fluorescence Indicates a Calcium-Dependent Interaction Between the Lipopeptide Antibiotic LY146032 and Phospholipid Membranes," *Biochemistry* 27: 4639-4645 (1988).

Lakey, Jeremy H. et al. "The Lipopeptide Antibiotic A21978C Has a Specific Interaction With DMPC Only in the Presence of Calcium Ions," *Biochimica et Biophysica Acta* 985: 60-66 (1989).

Lee, Belle L. et al. "Effect of Protein Binding of Daptomycin on MIC and Antibacterial Activity," *Antimicrobial Agents and Chemotherapy* 35: 2505-2508 (1991).

Liebowitz, Lynne D. et al. "In Vitro Selection of Bacteria Resistant to LY146032, a New Cyclic Lipopeptide," *Antimicrobial Agents and Chemotherapy* 32: 24-26 (1988).

Maget-Dana, Régine et al. "A Comparative Monomolecular Film Study of Antibiotic A21978C Homologues of Various Lipid Chain Length," *Biochimica et Biophysica Acta* 962: 201-207 (1988).

Zambias, Robert A. et al. "Preparation and Structure-Activity Relationships of Simplified Analogues of the Antifungal Agent Cilofungin: A Total Synthesis Approach," *Journal of Medicinal Chemistry* 35: 2843-2855 (1992).

Zmijewski, M.J. et al. "Role of Branched Chain Fatty Acid Precursors in Regulating Factor Profile in the Biosynthesis of A21978 C Complex," *Journal of Antibiotics* XXXIX: 1483-1485 (1986).

Applicants request that the cited documents be (1) fully considered by the Examiner during the course of examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

Respectfully submitted,

Karen E. Brown  
James F. Haley, Jr. (Reg. No. 27,794)  
Attorney for Applicants  
Karen E. Brown (Reg. No. 43,866)  
Agent for Applicants  
c/o FISH & NEAVE  
1251 Avenue of the Americas  
New York, NY 10020-1104  
Tel: (212) 596-9000

I Heroby Certify that this  
Correspondence is being  
Deposited with the U.S.  
Postal Service as First  
Class Mail in an Envelope  
Addressed to: ASSISTANT  
COMMISSIONER FOR  
PATENTS  
WASHINGTON, D.C. 20231 on

Karen E. Brown 28, 2001  
Signature of Person Signing